UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,247	04/13/2007	Ge Ming Lui	266622	6960

23548 7590 09/01/2010

LEYDIG VOIT & MAYER, LTD
700 THIRTEENTH ST. NW
SUITE 300
WASHINGTON, DC 20005-3960

EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
09/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCpatent@leydig.com
Chgpatent@leydig.com

Office Action Summary	Application No.	Applicant(s)	
	10/575,247	LUI, GE MING	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-80* is/are pending in the application.

4a) Of the above claim(s) *44-47,49-57 and 62-64* is/are withdrawn from consideration.

5)☒ Claim(s) *65,69 and 71-77* is/are allowed.

6)☒ Claim(s) *40,42,43,48,58-61,66-68,70 and 78-80* is/are rejected.

7)☒ Claim(s) *41 and 71* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response of 6/15/2010 has been received and entered into the application file. Claims 1-39 have been cancelled; new claims 40-80 have been added.

Applicants' response has been fully considered. The cancellation of claims 1-39 has rendered the rejections thereagainst moot; however, some of the rejections are newly applied against the corresponding new claims. Arguments against those rejections/objections newly applied to the corresponding new claims have been addressed below.

Election/Restrictions

Claims 44-47, 49-57 and 62-64 substantially correspond to original claims 5-8, 10-18 and 23-25, and thus are withdrawn from consideration, pursuant to 37 CFR 1.42(b), as being directed to non-elected inventions. Election was made without traverse in the reply filed on 10/5/2009 is acknowledged.

Formal Matters

Please note that new claims should not be amended, as amendments are made vis-à-vis the previous claim version, if a claim is new, there is no previous claim version. Therefore the amendment of 6/15/2010 could be considered non-compliant with 37 CFR 1.121(c); however, in the interest of compact prosecution the amendment will not be held non-responsive. Words that are ~~striked-through~~ will be considered deleted, words that are underlined will be considered added, the actual strike-throughs and underlines are not being considered part of the claim text. Further responses must be compliant with 37 CFR 1.121(c).

Claim Objections

The new claims presented address and correct most of the causes of the previous objections, however, claim 71 (which corresponds to original claim 31) still has the error of the original claim, and thus the objection is applied anew as follows:

Thus claim 71 is objected to because of the following informalities:

Claim 71 must start with a capital letter and an article of speech, i.e. "A laboratory apparatus..." Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The new claims presented address and correct most of the causes of the previous rejections; however, claims 48, 60, 61, 67, 68, 70 and 80 (which corresponds to claims 9, 21, 22, 27, 28, 30 and 39, respectively) still have the errors of the original claims and thus the rejections are applied anew as follows:

Claims 48, 60, 61, 67, 68, 70 and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 48, 60, 61, 67 and 68 are held as indefinite because of the recitation of the term "RGDS." While it is acknowledged that the RGDS *peptide* was well known in the art, it remains that Applicants have not identified "RGDS" as the RGDS *peptide*, thus it cannot be unequivocally concluded that "RGDS" refers to the well-known peptide Arg-Gly-Asp-Ser. Nowhere does the specification define RGDS as a *peptide*, thus there is no support that the term necessarily refers to the well known *peptide*

sequence, as opposed to being an internal reference for any other component (i.e. such as in the case of "May Polymer"). Thus the metes and bounds of the claim can therefore not be determined.

Furthermore, while it is acknowledged that the RGDS *peptide* was well known in the art at the time of filing, it remains that 37 CFR 1.821 requires that peptide sequences of greater than four amino acids must be identified by a proper SEQ ID NO. It is noted that US Patent 7,517,954, which Applicants reference, refers to an "RGD-enriched gelatine," thus the patent is not reciting an isolated RGD peptide (however, RGD is only three amino acids and thus would not require a SEQ ID NO. under 37 CFR 1.821), but rather an RGD-enriched gelatine, several sequence listings are provided in the '954 patent. Patents which recite the RGDS peptide as an individual peptide do need to provide a SEQ ID NO, see US Patent 5,811,394).

Claims 60, 61, 67 and 68 are held as indefinite because the Markush-type language does not clearly define the alternative reagents. A Markush-type claim recites alternatives in a format such as "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). The instant claim is in the format "selected from the group consisting of A, B, C, D, E *and* F *or* G." Thus the claim fails to clearly identify the group from which the polymer must be selected.

Applicants have not specifically addressed this rejection.

Claim 70 is rejected because the recited species of "slides" does not appear to correlate with parent claim 69, as slides do not have an inside and outside surface, wherein the inside surface may be coated with a diamond-like coating.

Applicants have not specifically addressed this rejection.

Claim 80 is rejected as lacking antecedent basis for the limitation "the synthetic biodegradable polymer" in the first through second line of the claim, claim 78, from which claim 80 depends, does not define the synthetic polymer as biodegradable. It appears claim 80 should depend from claim 79. Correction is required.

Claim 80 is further held indefinite because the Markush-type language does not clearly define the alternative species of polymers. A Markush-type claim recites alternatives in a format such as "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). The instant claim is in the format "selected from the group consisting of A, B, *or* C, *or* D *and* E." Thus the claim fails to clearly identify the group from which the polymer must be selected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-61, 66-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claims 59 and 66 each define the biopolymer as being comprised of chitosan *and/or* sodium alginate. Applicants have pointed to paragraph 0011 of the specification for support; however, upon review it is noted that the specification only provides support for the biopolymer binge chitosan *or* sodium alginate, not a combination thereof. Therefore, claims 59 and 66, in so far as they define the biopolymer as chitosan *and* sodium alginate, are rejected as

containing new matter. Claims 60, 61, 67 and 68 inherit the deficiencies of claims 59 and 66 and therefore are included in the rejection.

An amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed. In re Wright, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989). Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection based on Lu et al (Bio-Medical Materials and Engineering, 1993) is not applied anew against the instant laboratory apparatus claims because the instant claims require that the laboratory apparatus comprise an inner surface which is coated with a film of Diamond-like carbon *layered over a biopolymer coating*. Lu et al does not teach a biopolymer coating present between the Petri dish (laboratory apparatus) surface and the DLC coating.

The rejection based on Ignatius et al (Journal of Biomedical Material Research, 1998) is not applied anew against the instant laboratory apparatus claims because the instant claims require the laboratory apparatus to comprise an inner surface which is coated with a film of Diamond-like carbon *layered over* a biopolymer coating. The coverslips (laboratory apparatus) of Ignatius et al are coated with a poly-l-lysine layer (a biopolymer coating) layered over the Diamond-like carbon coating; thus the layers are provided in the reverse order.

The following are new grounds of rejection, necessitated by amendment:

Claim 78 is rejected under 35 USC 102(b) as being anticipated by Steffen et al (Surface and Interface Analysis, 2000).

Steffen et al disclose biocompatible polymeric substrates coated with diamond-like carbon coatings. Specifically, Steffen et al disclose providing substrate materials PTFE vascular prosthesis and polystyrene films and exposing the substrates to conditions which resulted in deposition of a hydrogenated diamond-like carbon film. The DLC-coated substrates were then further exposed to ammonia gas and subsequently to heparin solution to result in covalent attachment of heparin molecules to the DLC films (See Steffen et al, Pg. 388, "Experimental").

The resulting product comprised the PTFE vascular prosthesis or polystyrene film substrates (each of which read on synthetic biopolymers per the definition of the instant specification), coated with a diamond-like carbon film which is functionalized with heparin. The DLC-coated PTFE prosthesis and PS films anticipate the product of instant claim 78.

Claims 58 and 78-80 are rejected under 35 USC 102(b) as being anticipated by Woo et al (WO 01/43790).

Woo et al disclose medical devices that comprise a biocompatible polymer, wherein at least a portion of the biocompatible polymer is coated with a diamond-like carbon (DLC) coating (See Woo et al, Pg. 3, ln 1-8). Woo et al disclose a number of biocompatible polymers to which the DLC coating can be applied, including polymethylmethacrylate (Pg. 17, line 10) and gelatin (Pg. 17, line 25).

Polymethylmethacrylate is a synthetic, biodegradable acrylic polymer. A polymethyl-methacrylate polymer at least partially coated with a DLC coating anticipates claims 78-80. Please note the intended use recited in the preamble of claim 78 ("for the growth and attachment of cells") does not limit the structure of the composition in any manner, because the body of the claim sets forth all structural

limitations of the product, the intended use recited in the preamble is of no significance to claim construction and is not considered a limitation. Though the product of Woo et al has a different intended use, it is structurally the same, and thus anticipates the claimed product.

Gelatin is considered a semi-solid biopolymer (giving the term 'semi-solid' is broadest reasonable interpretation consistent with the art). Gelatin at least partially coated with a DLC coating therefore anticipates claim 58. It is noted that the ability to support neuronal growth is an inherent property of the DLC coating (as evidenced by Applicants); therefore, any substrate (including semi-solid gelatin) coated with DLC is *capable of* supporting neuronal cell growth. Again, because the body of the claim sets forth all structural limitations of the product, the intended use ("for supporting the growth and replication of neural cells"), recited in the preamble, is of no significance to claim construction and is not considered a limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Regarding the rejection under 35 USC 103(a), Applicants have traversed on the grounds that the claimed composition is distinct from that taught by Ignatius et al because the order of the biopolymer and the DLC coating (on the substrate) are different than the order in the claimed product. Furthermore, Applicants have traversed on the grounds that the deficiencies are not cured by Lu et al because the materials disclosed by Lu et al (specifically polycarbonate, polyethylene and polyurethane) are not examples of biopolymers, as required by the claims, and exemplified in Applicants' specification, as they

are neither biodegradable nor water-soluble. Thus, it appears Applicants are asserting that 'biopolymers' within the scope of their claims, must be biodegradable and water-soluble.

Applicants' arguments have been fully considered, but are not found persuasive. The rejection is applied anew over claims 40, 42, 43 and 78.

It is noted that none of claims 40, 42, 43 or 78 require the presence of a biopolymer between the substrate and the DLC coating, thus the argument that Ignatius et al does not disclose such is immaterial to the rejection at hand.

Furthermore, regarding the argument that none of polycarbonate, polyethylene and polyurethane are 'biopolymers' because they are neither biodegradable nor water-soluble, it is respectfully submitted that Applicants are arguing limitations not in the presently examined claims. There is no evidence of record to support that "biopolymers" would be ordinarily understood by persons of ordinary skill in the art to be both biodegradable and water soluble. In fact, the instant specification states that "biopolymers" includes both naturally occurring and synthetic polymers (See ¶0011). Absent recitation of identifying structural characteristics or functional properties linked to shared structures, the genus of 'biopolymers' is not limited to biodegradable and water-soluble polymers. Therefore, polycarbonate, polyethylene and polyurethane, as taught by Lu et al, are all examples of suitable biopolymers which may have been routinely substituted for the glass coverslips of Ignatius et al to receive the hydrogen-free DLC coating.

Claims 40, 42, 43 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignatius et al (Journal of Biomedical Material Research, 1998), in view of Lu et al (Bio-Medical Materials and Engineering, 1993).

Ignatius et al is disclose a method of depositing hydrogen-free, diamond-like carbon coating onto glass coverslips, and then further coating the same coverslips with an additional layer of ECM material, such as laminin; the double-coated substrates were then used to support attachment and growth of neural

cells. In disclosing the method, Ignatius et al necessarily disclose the hydrogen-free DLC-coated coverslips, per se.

Ignatius et al differ from the improved surface of claims 40, 42 and 43 in that Ignatius et al use glass coverslips, not biopolymer substrates.

However, given that the level of skill of the artisan in the field of cell biology is extremely high, being that of accomplished scientists having experience with cell culture technique, usually holding advanced degrees, it is submitted that the differences between the teachings of Ignatius et al and the current invention would have been found *prima facie* obvious to the artisan of ordinary skill at the time the invention was made based on the knowledge generally available to said artisans and the teachings of the prior art.

Specifically, substitution of an alternative substrate materials, such as known synthetic plastics, for the glass coverslips would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made. Lu et al is relied upon to evidence that cells are routinely grown on plastic tissue culture ware, such as polyethylene, polyurethane and polycarbonates; Lu et al further evidence that diamond-like carbon coatings can successfully be deposited on such plastic culture ware (See Lu et al, "Introduction"). Such culture ware was readily available in a variety of configurations, sizes and forms, including tissue culture flasks (which may be considered to be in sheet form) and microparticles. Therefore, because both Ignatius et al and Lu et al disclose depositing diamond-like carbon coatings on substrates for subsequent use in *in vitro* cell culture, it would have been obvious to one having ordinary skill in the art to substitute one substrate material (the synthetic biopolymers taught by Lu et al) for another (the glass coverslips taught by Ignatius et al). One would have had a reasonable expectation of successfully using synthetic biopolymer substrates because Lu et al state that plastic materials are capable of receiving DLC-coatings. It has been held that substitution of one element for another known in the field is considered to be obvious, absent a showing that the result of the substitution yields more than

predictable results. See *KSR International Co. v Teleflex Inc* 82 USPQ2d 1385 (US 2007) at page 1395. Therefore the improved surfaces of claims 40, 42, 43 and 78 are unpatentable over the teachings of Ignatius et al in view of Lu et al.

Allowable Subject Matter

Claim 41 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 48, 60, 61, 67, 68 and 70 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Primary Examiner, Art Unit 1651